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(62) Application number of the earlier application in accordance with Art. 76 EPC: **92900780.5**

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(54) Blunt tip surgical needle

(57) A surgical needle (10) for use in suturing non-cutaneous soft tissues of the body. The surgical needle (10) includes a needle shaft (11) and a needle tip (12) formed of a rigid material suitable for use inside the body. The needle tip (12) has a body portion (14) integrally formed with and extending from the needle shaft (11) and is tapered along its length. The needle tip (12) is further provided with a blunt head (16) which together with the body portion (14) defines a continuously smooth outer surface lacking any sharp cutting edges. The blunt head (16) is adapted to penetrate muscle and fascia, muscle alone, adipose, pericostal tissue and other non-cutaneous soft tissues of the body while at the same time preventing skin penetration of the gloved hand of an operator.

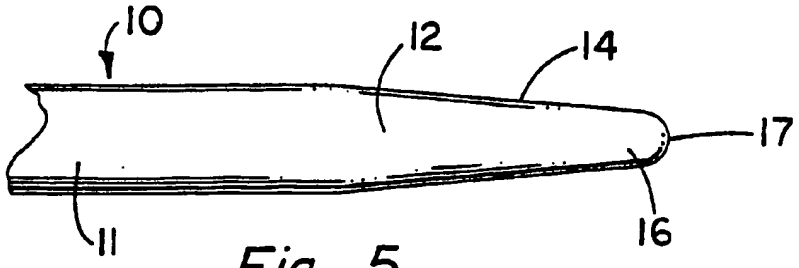

Fig. 5

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PARTIAL EUROPEAN SEARCH REPORT

which under Rule 45 of the European Patent Convention shall be considered, for the purposes of subsequent proceedings, as the European search report

Application Number EP 96 11 2714

DOCUMENTS CONSIDERED TO BE RELEVANT

Category	Citation of document with indication, where appropriate, of relevant passages	Relevant to claim	CLASSIFICATION OF THE APPLICATION (Int.Cl.6)
X Y	US-A-2 008 251 (HILLEBRAND) * page 1, left-hand column, line 1 - line 6 * * page 1, right-hand column, line 29 - line 30; claims; figures 4-7 *	1,16 2-8, 17-19	A61B17/06
Y A	WO-A-90 01349 (UTTERBERG) * page 5, line 9 - page 6, line 3; figure 2 * * page 8, line 13 - line 15 * * page 11, line 15 - page 12, line 10; claims 1,3,4; figures 2-6 *	2-8, 17-19 9	
X	DD-A-215 233 (VEB NADELWERK ICHTERSHAUSEN) * abstract * * page 8, line 11; figure 1 *	1,2,16, 17	
X A	US-A-4 541 427 (KOSS) * column 3, line 30 - line 33 * * column 4, line 4 - line 17; claims 5,13; figure 3 *	1,2,16, 17 7-9	TECHNICAL FIELDS SEARCHED (Int.Cl.6) A61B

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INCOMPLETE SEARCH

The Search Division considers that the present European patent application does not comply with the provisions of the European Patent Convention to such an extent that it is not possible to carry out a meaningful search into the state of the art on the basis of some of the claims

Claims searched completely :

Claims searched incompletely :

Claims not searched :

Reason for the limitation of the search:

see sheet C

Place of search	Date of completion of the search	Examiner
THE HAGUE	26 November 1996	Klein, C

CATEGORY OF CITED DOCUMENTS

X : particularly relevant if taken alone
Y : particularly relevant if combined with another document of the same category
A : technological background
O : non-written disclosure
P : intermediate document

T : theory or principle underlying the invention
E : earlier patent document, but published on, or after the filing date
D : document cited in the application
L : document cited for other reasons

& : member of the same patent family, corresponding document

EPO FORM 1503 03.82 (P04C07)

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PARTIAL EUROPEAN SEARCH REPORT

Application Number EP 96 11 2714

DOCUMENTS CONSIDERED TO BE RELEVANT			CLASSIFICATION OF THE APPLICATION (Int.Cl.6)
Category	Citation of document with indication, where appropriate, of relevant passages	Relevant to claim	
X A	US-A-2 786 619 (MARION) * column 1, line 42 - line 55; figure 5 *	1,16 9	
X	US-A-3 094 123 (KURTZ) * column 2, line 56 - line 60; figure 2 *	1,16	
A	DE-C-590 192 (ROEDER) * page 1, right-hand column, line 52 - line 54; claim 4; figures 4,5 *	1,2,7,8, 16,17	
A	US-A-4 966 143 (MEINERSHAGEN) * the whole document *	1,16	
A	US-A-3 789 852 (KIM) * column 4, line 63 - line 66; claim 2; figure 12 *	1,16	TECHNICAL FIELDS SEARCHED (Int.Cl.6)
A	GB-A-205 105 (CHARNAUX)		
A	US-A-3 613 684 (SHERIDAN)		
A	US-A-4 710 180 (JOHNSON)		

EPO FORM 1503 03.82 (P04C10)

European Patent Office

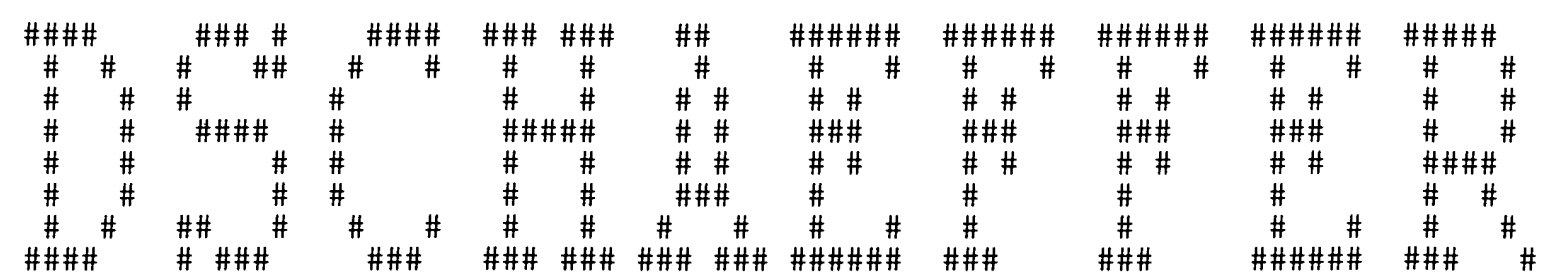
EP 96 11 2714 - C -

INCOMPLETE SEARCH

The Search Division considers that the present European patent application does not comply with the provisions of the European Patent Convention to such an extend that it is not possible to carry out a meaningfull search into state of the art on the basis of some of the claims.

Claims searched completely: 1-9,16-19
Claims searched incompletely:
Claims not searched: 10-15,20-25

Reason for the limitation of the search: Methods for treatment of the human body by surgery (see EPC art. 52 (4)).



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Remarks:
This application was filed on 07 - 08 - 1996 as a divisional application to the application mentioned under INID code 62.

(54) Blunt tip surgical needle

(57) A surgical needle (10) for use in suturing non-cutaneous soft tissues of the body. The surgical needle includes a needle shaft (11) and a needle tip (12) formed of a rigid material suitable for use inside the body. The needle tip has a body portion (14) integrally formed with and extending from the needle shaft and is tapered along its length. The needle tip is further provided with a blunt head (16) which together with the body portion defines a continuously smooth outer surface lacking any sharp cutting edges. The blunt head is adapted to penetrate muscle and fascia, muscle alone, adipose, pericostal tissue and other non-cutaneous soft tissues of the body while at the same time preventing skin penetration of the gloved hand of an operator.

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Description

BACKGROUND OF THE INVENTION

Field of the Invention:

The present invention relates generally to the field of surgical instruments and, more specifically, to surgical needles for suturing wounds.

Description of the Art:

In recent years, there has been an increasing awareness of the problems associated with accidental sticking of medical personnel with suturing and syringe needles. Before the advent of biological warfare contaminants and the spreading of infectious health hazards such as hepatitis B (HBV), human immunodeficiency virus (HIV) infection and acquired immune deficiency syndrome (AIDS), the consequences of sustaining a needle stick wound were not considered serious. However, the knowledge that infectious diseases such as the AIDS virus can be spread by an accidentally inflicted needle-stick from a contaminated needle administered to a person having the AIDS virus has done much to change this belief. Accordingly, there has been an increasing amount of activity in the area of addressing this problem. For example, one prior art needle assembly contains a blunting member which is movable, either by fluid flow through the needle or by mechanical pressure, from a retracted position in which the blunting member does not interfere with the puncture tip of the needle, to an extended position attained after use in which the blunting member extends beyond the punture tip and thereby blunts the needle. The prior art discloses further examples of shield or guard type assemblies for syringe needles.

While the devices disclosed above and other similar type devices may be useful for hypodermic syringe needles which are intended to be disposed of after a single "stick", it is not a practicable solution for use with surgical needles since such needles must make repeated "sticks" into the body. While surgeons are highly trained and skilled individuals, the possibility of an accidental stick from a surgical needle is still present. Even a highly skilled surgeon can eventually become tired or, as in trauma situations, in a hurry at the end of a long operation and thus more prone to such an occurrence. Then too, it is not uncommon that a less experienced individual in the operating room team is assigned to close the wound.

The present invention is intended to decrease the potential transmission of all infectious agents, including those referred to above, in situations where accidental needle stick is the means for such transmission.

SUMMARY OF THE INVENTION

The present invention is a surgical needle for use in suturing non-cutaneous soft tissues of the body. In a preferred embodiment thereof, the present invention comprises a needle shaft and a needle tip formed of a rigid material suitable for use inside the body. The needle tip has a body portion integrally formed with and extending from the needle shaft. The body portion is tapered along the length thereof. The needle tip is further provided with a blunt head adapted to penetrate muscle and fascia, muscle alone, adipose, pericostal tissue and other non-cutaneous soft tissues of the body while at the same time decreasing potential skin penetration of the gloved hand of an operator and operating personnel such as surgeons, surgeon assistants, scrub and circulating nurses, fabric care and housekeeping personnel.

As additional features, the blunt head may have a part spherical shape and a vertex which forms a portion of the part spherical shape. Further, the blunt head may have a diameter of curvature which is in a range from about 25% to 62% of the diameter of the needle shaft and the needle tip may be formed so as to have a continuously smooth outer surface lacking any sharp cutting edges.

Accordingly, it is an object of the present invention to provide an improved surgical needle for use in suturing muscle and fascia, muscle alone, adipose, pericostal tissue and other non-cutaneous soft tissues of the body while at the same time significantly decreasing the probibility of skin penetration of the gloved hand of an operator.

Related objects and advantages of the present invention will become more apparent by reference to the following figures and detailed description.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 is a graph showing the relationship between penetration force and needle bluntness using data obtained from Table I.

FIG. 2 is a graph showing the variation in difference in resistance to penetration between gloved plantar skin and abdominal rectus muscle as a function of needle bluntness using data obtained from Table III.

FIG. 3 is a graph showing the variation in average penetration force as a function of needle bluntness using data obtained from Table III.

FIG. 4 is a side view of a preferred embodiment of the surgical needle of the present invention.

FIG. 5 is an enlarged fragmentary view of the tip portion of the surgical needle of FIG. 4.

FIG. 6 is an enlarged cross-sectional view taken along lines 6--6 in Figure 4.

FIG. 7 is an alternative embodiment of the enlarged cross-sectional view taken along lines 6--6 in Figure 4.

FIG. 8 is an enlarged cross-sectional view taken along lines 8--8 in Figure 4.

DESCRIPTION OF THE PREFERRED EMBODIMENT

For the purposes of promoting an understanding of the principles of the invention, reference will now be made to the embodiment illustrated in the drawings and specific language will be used to describe the same. It will nevertheless be understood that no limitation of the scope of the invention is thereby intended, such alterations and further modifications in the illustrated device, and such further applications of the principles of the invention as illustrated therein being contemplated as would normally occur to one skilled in the art to which the invention relates.

As used herein, the term "bluntness" is intended to refer to the relation between the diameter of curvature of the needle point or vertex to the diameter of the needle shaft. For comparison purposes, this relationship is expressed as a percentage. As an example, a needle having 50% bluntness is intended to describe a needle having a diameter of curvature at the vertex which is half the diameter of the needle shaft. The term "diameter of curvature" as used herein describes the hypothetical diameter of a fully spherical surface coincident with the part spherical surface which forms the vertex, or forwardmost point, of the needle. Thus, a totally sharp needle, i.e., a needle having 0% bluntness, has zero curvature present at the needle vertex.

A number of tests were conducted to determine whether there existed a blunt needle point configuration which would permit relatively easy penetration of soft non-cutaneous body tissues while providing increased protection against an unintended stick of the gloved hand of the operator. These included tests to determine the penetration force as a function of "bluntness" in muscle/fascia and in gloved palmar skin.

In a first series of tests, four groups of test results were obtained corresponding to the following four test specimens: (1) abdominal rectus muscle/fascia, (2) gloved palmar skin, (3) abdominal rectus muscle/fascia vs. gloved plantar skin, and (4) intercostal muscle. In each group of tests, eight needle point configurations were tested having a bluntness of 0%, 25%, 37%, 50%, 62%, 75%, 87%, and 100%. A sample set of six needles per each configuration were used for each of the first, second and fourth groups of tests, making a total of 48 needles for each of these groups of tests. In the third group of tests, a sample set of twelve needles was used for each needle configuration, making a total of 96 needles for this test group. All needles were type T-20 surgical needles manufactured by the Davis & Geck Division of American Cyanamid Company of Danbury, Conn., U.S.A. having a length of 1.891 inches, a wire diameter of .050 inches, and a curved shape having a radius of curvature along the needle shaft of 0.656 inches and an included angle of 165 degrees.

The first group of test results for the abdominal rectus muscle/fascia was conducted as follows. The skin overlying the abdominal fascia of a single cadaver was opened and retracted. The supra-umbilical abdominal rectus muscle with its anterior and posterior sheaths was then excised from the cadaver. Using this specimen, the force of penetration was measured for each of the needles in the sample. A total of three passes were made for each needle. In each pass, penetration was made away from the midline of the specimen so that the penetration sequence would always be fascia, muscle, then fascia.

In the second group of tests, skin from the palms of the same cadaver used in the first series of tests was harvested. The area harvested was bounded proximally by the skin crease at the wrist and distally by the base of the digits. A standard latex procedure glove was placed over the skin specimen in order to simulate unintended puncture of the surgeon's hand. The penetration sequence was glove, epidermis, dermis, and lastly, the back side of the latex glove. As with the first group of tests, the force of penetration was measured for each of the needles in the sample, with a total of three passes being made for each needle.

The goal in the third group of tests was to directly compare the penetration force of gloved skin as compared to that of abdominal rectus muscle/fascia using the same needle. Since all usable palmar skin had been harvested from the test cadaver in performing the previous group of tests and another suitable cadaver was unavailable, plantar skin was harvested from the test cadaver's feet. This skin is similar to the skin of the palm in that both are thick skin areas. Only the central non-weight bearing portion of the plantar skin was used. The rectus muscle and fascia was harvested from the same test cadaver from the umbilicus to just superior to the pubic bone. The rectus muscle/fascia tissue was penetrated first, followed by the gloved plantar skin. In order to assess the difference in penetration force of palmar skin versus plantar skin, several passes were made through some remaining palmar skin after the plantar skin had been penetrated. The results obtained indicated that the penetration force was approximately the same for the two skin specimens using the sharp (0% bluntness) needles, with the plantar penetration force increasing as the bluntness fo the needle increased (approximately twice the penetration force was necessary with a 62% dull needle). Again, the force

of penetration was measured for each of the needles in the sample. In this group of tests, one pass was made into both specimens with each needle.

For the fourth group of tests, intercostal muscle was harvested from the same cadaver from interspaces 3 through 5 at the mid-clavicular line. The specimen blocks also consisted of the pleural lining of the chest (parietal pleura). The force of penetration was measured for each of the needles in the sample, with a total of three passes being made for each needle.

Table 1 lists the results of each of the four groups of test results in this first series of tests. Each needle is identified in the table by the letter "D" prefixed by a number indicating the testing order. The penetration force is expressed in grams.

TABLE I

Group 1 results (Abdominal Rectus Fascia/Muscle):

0%	25%	37%
4D 80, 120, 80	3D 360, 680, 600	6D 880, 600, 600
7D 120, 120, 120	13D 840, 760, 1000	9D 920, 1120, 1000
19D 40, 80, 120	14D 640, 600, 600	12D 720, 840, 880
30D 80, 120, 80	20D 600, 520, 680	26D 1160, 760, 720
38D 80, 80, 80	31D 680, 720. 800	27D 520, 840, 840
40D 40, 80, 120	36D 840, 640, 840	41D 800, 600, 920

50%	62%
5D 920, 960, 1080	2D 640, 720, 600
11D 1560, 1000, 1080	10D 2040, 1200, 1600
25D 1040, 1160, 920	18D 1800, 1720, 1520
28D 1800, 1000, 1240	24D 1240, 1520, 1080
32D 720, 1120, 600	29D 1560, 920, 840
42D 920, 1400, 1360	39D 1200, 1520, 1200

75%	87%	100%
8D 2520, 2440, 1520	15D 2680, 2280, 2560	1D 2920, 1200, 2040
17D 1520, 1880, 1600	21D 1760, 1960, 2120	16D 2400, 2760, 3080
22D 2440, 1320, 1520	34D 2480, 2160, 1800	23D 1920, 1680, 2160
33D 2000, 1840, 1400	35D 1760, 1560, 2240	37D 2280, 3000, 3600
46D 2120, 1760, 1800	43D 2640, 2800, 2920	44D 2520, 1880, 2400
47D 2620, 2720, 2480	45D 1680, 2760, 3160	48D 2920, 2440, 2400

Group 2 results (Gloved Palmar Skin):

0%	25%	37%
8A 300, 500, 300	9A 900, 800, 500	4A 800, 1200, 900
10A 200, 200, 400	14A 300, 800, 800	19A 800, 700, 800
11A 600, 700, 700	15A 700, 700, 900	23A 1200, 1300, 1700
12A 400, 400, 400	44A 800, 800, 1000	32A 1000, 1000, 1200
27A 300, 700, 800	61A 600, 800, 700	33A 1200, 2000, 1800
31A 400, 600, 800	63A 900, 1400, 1200	35A 900, 1800, 800
37A 400, 700, 600	65A 800, 800, 800	42A 1600, 1500, 900
66A 200, 300, 400	69A 1300, 1300, 900	45A 800, 800, 1200
73A 100, 200, 200	74A 800, 700, 1100	46A 1300, 1800, 1900
83A 200, 300, 300	97A 500, 500, 500	56A 900, 900, 1000
85A 500, 400, 400	81A 700, 600, 600	59A 1000, 900, 1300
88A 200, 200, 200	91A 500, 600, 600	94A 900, 900, 1000

50%	62%
1A 1840, 2240, 1600	16A 1500, 1300, 1200
6A 1100, 1200, 1100	21A 1500, 2200, 2200
18A 1500, 1500, 1300	24A 2000, 1700, 1600
26A 1400, 1800, 1300	29A 1500, 1900, 1400
34A 1700, 1600, 1600	47A 2400, 2300, 3500
48A 1600, 1500, 2000	49A 3000, 2600, 2400
54A 1400, 2300, 2200	52A 1200, 1100, 2100
57A 900, 1300, 1600	55A 1400, 1200, 1800
68A 1800, 1400, 1500	58A 1300, 1900, 2100
75A 1200, 1000, 1200	60A 900, 1200, 1000
79A 1100, 1000, 1400	82A 1700, 1500, 1800
80A 1600, 1600, 2000	96A 2200, 2000, 2900

75%	87%	100%
2A 2900, 2800, 2700	5A 3600, 2300, 3600	22A 2400, 3000, 2900
3A 1600, 4500, 3900	13A 2700, 2400, 2300	25A 3100, 3600, 2300
7A 1800, 2200, 2700	17A 2700, 2900, 3300	30A 3400, 2800, 5600
20A 2200, 3200, 3200	28A 4600, 3100, 3000	40A 6000, 5100, 4000
36A 4800, 4500, 4200	39A 3900, 3000, 3200	43A 4900, 3200, 3400
38A 3200, 3500, 3600	41A 3300, 3500, 3400	51A 3100, 3000, 2900
50A 1900, 2400, 2000	64A 3900, 3200, 5500	62A 4900, 3100, 2700
53A 3100, 2200, 3100	76A 2400, 2600, 2800	67A 4900, 4500, 2900
71A 1400, 2300, 2000	84A 3800, 2800, 2700	70A 2800, 3300, 3200
72A 2100, 1800, 2600	89A 2200, 2000, 2200	87A 4200, 3200, 3000
78A 1800, 2000, 2300	93A 2300, 3000, 2100	90A 2500, 3400, 2700
86A 2100, 2200, 3500	95A 2400, 2900, 2800	92A 2800, 2400, 3300

Group 3 Results (Abdominal Rectus Muscle/Fascia vs. Gloved Plantar Skin):

0%	25%	37%
8B 50, 350	7B 550, 1200	6B 500, 800
9B 50, 400	10B 450, 1450	12B 350, 1600
19B 50, 300	21B 350, 900	16B 600, 1350
28B 150, 450	37B 700, 1150	20B 450, 1200
53B 200, 700	38B 450, 1100	24B 550, 1350
54B 50, 450	51B 250, 1150	30B 450, 1250
73B 100, 300	56B 300, 150	39B 350, 1050
75B 50, 300	60B 500, 1600	45B 550, 1400
77B 50, 500	65B 550, 1400	48B 350, 1300
90B 50, 400	83B 350, 1100	59B 800, 1750
89B 100, 550	84B 700, 1200	68B 700, 1200
91B 50, 250	85B 400, 1100	92B 400, 1200

50%	62%
1B 750, 2600	2B 650, 2450
5B 600, 3050	11B 500, 2850
13B 450, 1800	22B 850, 2400
25B 600, 2400	34B 750, 2750
32B 250, 2650	36B 850, 2500
35B 350, 1150	41B 900, 2150
40B 1000, 1850	46B 600, 3100
52B 500, 2450	61B 850, 2500
67B 550, 1900	67B 1100, 3750
70B 1400, 1750	79B 500, 3350
78B 600, 2250	81B 700, 3300
87B 750, 2300	94B 250, 3000

75%	87%	100%
4B 350, 3300	15B 700, 4850	3B 750, 5000+
14B 1500, 3000	26B 800, 5000+	17B 700, 5000+
18B 1150, 3600	29B 300, 4150	24B 1800, 5000+
23B 400, 3750	31B 900, 5000+	42B 300, 5000+
33B 1400, 4250	44B 1050, 4900	49B 1000, 5000+
43B 950, 3600	57B 1350, 5000+	62B 1550, 5000+
47B 1100, 4750	58B 1300, 5000+	64B 750, 5000+
50B 700, 2150	69B 1300, 2950	74B 1200, 5000+
55B 900, 4450	71B 2550, 4500	76B 600, 5000+
66B 900, 4950	80B 1350, 5000+	82B 1000, 5000+
72B 1900, 4500	88B 900, 5000+	86B 1550, 5000+
93B 1050, 4650	96B 1700, 4450	95B 1150, 5000+

Group 4 Results (Intercostal Fascia/Muscle):

0%	25%	37%
21C 40, 80, 80	9C 720, 480, 200	13C 800, 1000, 440
24C 40, 40, 80	15C 360, 200, 280	16C 320, 440, 480
36C 160, 200, 120	19C 200, 480, 200	20C 600, 440, 840
41C 80, 80, 80	34C 520, 240, 320	30C 200, 360, 280
43C 80, 80, 40	37C 400, 520, 200	31C 400, 560, 320
48C 40, 80, 40	39C 400, 240, 320	45C 440, 480, 480

50%	62%
8C 1040, 1440, 520	3C 880, 640, 600
14C 720, 480, 600	10C 480, 480, 880
22C 400, 400, 760	11C 1200, 880, 1600
27C 400, 320, 720	17C 800, 840, 840
29C 520, 480, 400	26C 720, 480, 440
42C 360, 440, 480	40C 400, 440, 720

75%	87%	100%
1C 1000, 880, 960	5C 1800, 920, 1160	4C 960, 1960, 1320
2C 1200, 600, 920	7C 1760, 2400, 1080	32C 1600, 760, 800
6C 920, 1200, 1600	23C 520, 600, 1000	35C 1840, 1800, 1000
12C 560, 1560, 760	28C 720, 1520, 1520	44C 1120, 720, 560
18C 520, 960, 560	33C 1360, 1000, 840	46C 880, 1600, 1000
25C 200, 480, 1120	38C 1400, 720, 600	47C 1720, 1160, 1360

The data set forth in Table I is shown in graph form in Figure 1, wherein resistance to penetration is plotted along the vertical axis and degree of tip bluntness, expressed as a percentage, is plotted along the horizontal axis. Proceeding from uppermost to lowest, the four curves in Figure 1 correspond to gloved plantar skin, gloved palmar skin, abdominal rectus muscle, and intercostal muscle, respectively. As can be seen with reference to Figure 1, at all bluntness settings both gloved palmer skin and gloved plantar skin exhibit a greater resistance to penetration than do abdominal rectus fascia/muscle or intercostal fascia/muscle. Further, as can be seen with reference to Figure 2, the difference in penetration force between gloved skin (plantar) and fascia/muscle (abdominal rectus) remains about the same for needle bluntness in the range between about 0 and 25%. However, as the degree of needle bluntness approaches about 25%, the difference in penetration force between gloved skin (palmar) and fascia/muscle (abdominal rectus) begins to increase. This difference in penetration force continues to increase throughout the remaining range of needle bluntness. It is also perceived from these tests that at bluntness settings greater than about 62% the resistance to penetration of

the type needle becomes sufficiently great in abdominal rectus and intercostal fascia/muscle that usage would be disfavored.

In a second series of tests, needles having bluntness settings in a range from 25% to 62% were tested in comparison with totally sharp needles having 0% bluntness. The specific bluntness settings tested were 0%, 25%, 37%, 50%, and 62%. Thirty-two penetration measurements were taken at each bluntness setting, broken into four test series identified as A, B, C and D. Each test series was done on a single cadaver. For each test, a needle was passed through muscle fascia and the required penetration force was recorded. Thus, this series of tests involved 160 needles. Table II shows the raw data obtained while Table III presents a statistical summary of the results of these tests. Figure 3 is a graph showing the variation in average penetration force as a function of needle bluntness using data obtained from Table III. In Table III "Avg" refers to the average force of penetration expressed in grams of the thirty-two tests conducted at each bluntness setting, while "SD" refers to the standard deviation of the test results.

TABLE II

Cadaver	Bluntness Setting	Abdom Rectus Muscle/Fascia	Gloved Palmar Skin	Difference
A	0%	80.0	340.0	260.0
B	0%	80.0	225.0	145.0
C	0%	145.0	285.0	140.0
D	0%	65.0	210.0	145.0
A	25%	345.0	835.0	490.0
B	25%	375.0	845.0	470.0
C	25%	860.0	1355.0	495.0
D	25%	350.0	775.0	425.0
A	37%	515.0	925.0	410.0
B	37%	400.0	1000.0	600.0
C	37%	1040.0	1660.0	620.0
D	37%	465.0	1080.0	615.0
A	50%	910.0	1480.0	570.0
B	50%	555.0	1370.0	815.0
C	50%	1450.0	2400.0	950.0
D	50%	665.0	1145.0	480.0
A	62%	595.0	1420.0	825.0
B	62%	695.0	1610.0	915.0
C	62%	1755.0	3495.0	1740.0
D	62%	775.0	1930.0	1155.0

TABLE III

Bluntness Setting	Muscle/Fascia	Gloved Skin	Difference
0%	Avg = 92.5	Avg = 265.0	Avg = 172.5
	SD = 41.2	SD = 70.9	SD = 69.2
25%	Avg = 482.5	Avg = 952.5	Avg = 470.0
	SD = 298.6	SD = 350.8	SD = 274.1
37%	Avg = 605.0	Avg = 1166.3	Avg = 561.3
	SD = 325.6	SD = 399.2	SD = 350.8
50%	Avg = 895.0	Avg = 1598.8	Avg = 703.8
	SD = 492.7	SD = 605.7	SD = 445.6
62%	Avg = 955.0	Avg = 2113.8	Avg = 1158.8
	SD = 538.5	SD = 969.4	SD = 619.6

It is perceived that the degree of safety provided to an operator by a particular needle configuration is directly related to the magnitude of difference in the penetration force needed to pierce the target body tissues and the gloved hand of the operator. As is indicated by the data in Table III, a totally sharp needle having 0% bluntness requires an average of 172.5 grams greater penetration force to penetrate gloved skin as compared to muscle fascia. This "safety factor" of 172.5 grams is of course insufficient in many instances in preventing accidental sticks of the gloved hand of the operator. The Table III results show that needles having a bluntness in the 25-62% range exhibit a much greater magnitude of difference in the penetration force needed to pierce the target body tissues and the gloved hand of the operator than sharp needles (i.e., needles having 0% bluntness).

Table IV indicates the average percent improvement in the safety factor provided by 25-62% blunt needles over sharp (0% blunt) needles, based on the Tables II and III data. The average percent improvement in the safety factor is defined by the following formula wherein A_{sf} is the average percent improvement in the safety factor, P_b is the average gloved skin penetration force at bluntness setting b, and P_o is the average gloved skin penetration force for a sharp (0% blunt) needle:

$$A_{sf} = (P_b/P_o) \times 100$$

TABLE IV

Bluntness Setting	P_o	P_b	Improvement
25%	265.0	952.5	359.4%
37%	265.0	1166.3	440.1%
50%	265.0	1598.8	603.3%
62%	265.0	2113.8	797.6%

Table V shows the minimum percent improvement in safety, defined by the following formula:

$$M_{sf} = (P_b^*/P_o) \times 100$$

In the above formula, M_{sf} is the minimum percent improvement in the safety factor. P_b^* is the minimum gloved skin penetration force at bluntness setting b calculated by subtracting the standard deviation in penetration force at blunt-

ness setting b from the average penetration force at bluntness setting b. Thus, 84% of the penetrations at bluntness setting b will be higher than P_b^*. P_o is the average gloved skin penetration force for a sharp (0% blunt) needle.

TABLE V

Bluntness Setting	P_o	P_b^*	Improvement
25%	265.0	601.7	227.1%
37%	265.0	767.1	289.5%
50%	265.0	993.1	374.8%
62%	265.0	1144.4	431.8%

A preferred embodiment of the surgical suture needle of the present invention, incorporating the desired safety characteristics is generally indicated at 10 in Figures 4 and 5. The needle 10 has a shaft portion 11 having a uniform outer diameter, and a tip portion 12 integrally formed with shaft portion 11 and extending distally therefrom. In order to provide stability and control of the needle 10 during use, the shaft portion 11 may have a flat pressed circular cross section such as shown in Figure 6 or, alternatively, a modified square cross sectional shape such as shown in Figure 7. In the needle 10 of Figure 4 the shaft portion 11 is curved and possesses a constant radius of curvature. This configuration is, however, not critical to the present invention and shaft portion 11 may therefore assume any straight and/or curved configuration which is considered suitable for the particular purpose that is intended. Both the shaft portion 11 and tip portion 12 are rigidly formed of a suitable material for suture needle use inside the body, such as surgical grade steel. The needle tip portion 12 has an essentially circular cross sectional shape, as shown in Figure 8, and a tapered body 14. The needle tip portion 12 terminates in a blunt head 16 which is configured to permit piercing of muscle and fascia, muscle alone, adipose, pericostal tissue and other non-cutaneous soft tissues of the body while preventing skin penetration of the gloved hand of an operator. As can be best appreciated with reference to Figure 5, head 16 preferably has a part spherical shape which encompasses vertex 17 of tip portion 12. Other curved shapes may also be employed as suitable configurations for head 16, so long as there are no sharp edge surfaces.

It should be noted that the surgical needle of the present invention is specifically designed such that it is not suitable for suturing cutaneous tissues. Accordingly, based upon the test results obtained, it is considered important that blunt head 16 have a minimum diameter of curvature which is at least 25% of the diameter of the needle shaft portion 11 and a maximum diameter of curvature which no greater than about 62% of the diameter of the needle shaft. Within this range, it is perceived that needles having a bluntness which is toward the higher end of the range will be especially preferred as they offer a greater safety factor while still being acceptable for use. Further, the diameter of the needle shaft should be in a range of about .026" to .050" with the diameter of curvature of the needle tip ranging between about .006" to about .031". In addition, it is considered critical that the entire needle tip portion has a continuously smooth outer surface lacking any discontinuities or sharp cutting edges.

In practice, the surgical suture needle of the present invention may be used to close non-cutaneous soft tissues of the body employing the same techniques used with conventional suture needles. However, since the cutaneous tissues of the wound cannot be closed with the blunt tip needle, another closing technique must be used to complete the wound closure. This does not pose a problem, however, in that it is quite common to employ different closing techniques for closing the cutaneous and non-cutaneous tissues in a wound. For example, the needle of the present invention may be used to close the non-cutaneous tissues while final closure of the cutaneous tissues may be accomplished by conventional stapling techniques.

It is perceived that the blunt needle of the present invention may, in addition to reducing the risk of infectious disease transmission by reducing the risk of an accidental needle stick, also serve to reduce the risk of needle contamination by reducing the amount of bleeding caused by the needle. Decreased bleeding occurs because the blunt needle is more likely to simply push blood vessels aside rather than penetrate them as it is being advanced in the body.

While the invention has been illustrated and described in detail in the drawings and foregoing description, the same is to be considered as illustrative and not restrictive in character, it being understood that only the preferred embodiment has been shown and described and that all changes and modifications that come within the spirit of the invention are desired to be protected.

Claims

1. A surgical needle (10) for use in suturing non-cutaneous soft tissues of the body, comprising:

a needle shaft (11); and

a needle tip (12), said needle shaft (11) and needle tip (12) integrally formed of a rigid material suitable for use inside the body and containing no fluid passages therethrough, said needle tip (12) having a body portion (14) integrally formed with and extending from said needle shaft (11), said body portion (14) being tapered along the length thereof, said needle tip (12) further having a blunt head (16) adapted to penetrate muscle and fascia, muscle alone, adipose, pericostal tissue and other non-cutaneous soft tissues of the body while preventing skin penetration of the gloved hand of an operator wearing a surgical glove.

2. The surgical needle of claim 1 wherein said needle tip (12) has a continuously smooth outer surface lacking any sharp cutting edges and said blunt head (16) has a part spherical shape and a vertex which forms a portion of said part spherical shape.

3. The surgical needle of claim 2 wherein said blunt head (16) has a diameter of curvature which is in the range of 25% to 62% of the diameter of said needle shaft and said diameter of curvature is at least about 0.15 mm (0.006").

4. The surgical needle of claim 1 wherein the diameter of said needle shaft (11) is in a range of about 0.66 mm to 1.27 mm (0.026" to 0.050"), and the diameter of curvature of said needle tip (12) is no greater than about 0.79 mm (0.031").

5. The surgical needle of claim 1 wherein the diameter of said needle shaft is in a range of about 0.66 mm to 1.27 mm (0.026" to 0.050").

6. The surgical needle of claim 4 wherein the diameter of curvature of said curved surface is in a range of about 25% to about 62% of the diameter of said needle shaft.

7. The surgical needle of claim 6 wherein said needle tip has a continuously smooth outer surface lacking any sharp cutting edges and said blunt head has a part spherical shape and a vertex which forms a portion of said part spherical shape.

8. The surgical needle of claim 7 wherein said needle tip has a generally circular cross-section.

9. The surgical needle of claim 8 wherein said needle shaft has a generally flat pressed circular cross-section along at least a portion of the length in order to facilitate stability in a needle holder.

10. A method of decreasing the transmission of infectious diseases caused by accidental needle stick during suturing of soft non-cutaneous tissues of the body, comprising the steps of:

piercing the non-cutaneous tissues with a suture needle; and

preventing skin penetration of the gloved hand of an operator by said suture needle, said prevention step being accomplished by employing a suture needle having a blunt tip.

11. The method of claim 10 wherein said prevention step is accomplished by employing a suture needle having a blunt tip formed so as to provide a safety factor of at least 200% over a needle having 0% bluntness.

12. The method of claim 10 wherein said prevention step is accomplished by employing a suture needle having a blunt tip formed so as to provide a safety factor of between about 200% to 800% over a needle having 0% bluntness.

13. A method of closing a body wound, comprising the steps of:

closing the non-cutaneous tissues by piercing the non-cutaneous tissues with a suture needle;

preventing skin penetration of the gloved hand of an operator by said suture needle, said prevention step being accomplished by employing a suture needle having a blunt tip; and

closing the cutaneous tissues by a conventional closure technique such as stapling, cuticular needle closure, adhesive tape, and combinations thereof.

14. The method of claim 13 wherein said prevention step is accomplished by employing a suture needle having a blunt tip formed so as to provide a safety factor of at least 200% over a needle having 0% bluntness.

15. The method of claim 13 wherein said prevention step is accomplished by employing a suture needle having a blunt tip formed so as to provide a safety factor of between about 200% to 800% over a needle having 0% bluntness.

16. A surgical needle for use in suturing non-cutaneous soft tissues of the body, comprising:

a needle shaft; and
a needle tip, said needle shaft and needle tip integrally formed of a rigid material suitable for use inside the body and containing no fluid passages therethrough, said needle tip having a body portion integrally formed with and extending from said needle shaft, said body portion being tapered along the length thereof, said needle tip further having a blunt head adapted to penetrate muscle and fascia, muscle alone, adipose, pericostal tissue and other non-cutaneous soft tissues of the body while preventing skin penetration of the gloved hand of an operator.

17. The surgical needle of claim 16 wherein said needle tip has a continuously smooth outer surface lacking any sharp cutting edges and said blunt head has a part spherical shape and a vertex which forms a portion of said part spherical shape.

18. The surgical needle of claim 17 wherein said blunt head has a diameter of curvature which is in the range of 25% to 62% of the diameter of said needle shaft and said diameter of curvature is at least about .006".

19. The surgical needle of claim 16 wherein the diameter of said needle shaft is in a range of about .026" to .050" and the diameter of curvature of said needle tip is no greater than about .031".

20. A method of decreasing the transmission of infectious diseases caused by accidental needle stick during suturing of soft non-cutaneous tissues of the body, comprising the steps of:

piercing the non-cutaneous tissues with a suture needle; and
preventing skin penetration of the gloved hand of an operator by said suture needle, said prevention step being accomplished by employing a suture needle having a blunt tip.

21. The method of claim 20 wherein said prevention step is accomplished by employing a suture needle having a blunt tip formed so as to provide a safety factor of at least 200% over a needle having 0% bluntness.

22. The method of claim 21 wherein said prevention step is accomplished by employing a suture needle having a blunt tip formed so as to provide a safety factor of between about 200% to 800% over a needle having 0% bluntness.

23. A method of closing a body wound, comprising the steps of:

closing the non-cutaneous tissues by piercing the non-cutaneous tissues with a suture needle;
preventing skin penetration of the gloved hand of an operator by said suture needle, said prevention step being accomplished by employing a suture needle having a blunt tip; and
closing the cutaneous tissues by a conventional closure technique such as stapling, cuticular needle closure, adhesive tape, and combinations thereof.

24. The method of claim 23 wherein said prevention step is accomplished by employing a suture needle having a blunt tip formed so as to provide a safety factor of at least 200% over a needle having 0% bluntness.

25. The method of claim 23 wherein said prevention step is accomplished by employing a suture needle having a blunt tip formed so as to provide a safety factor of between about 200% to 800% over a needle having 0% bluntness.

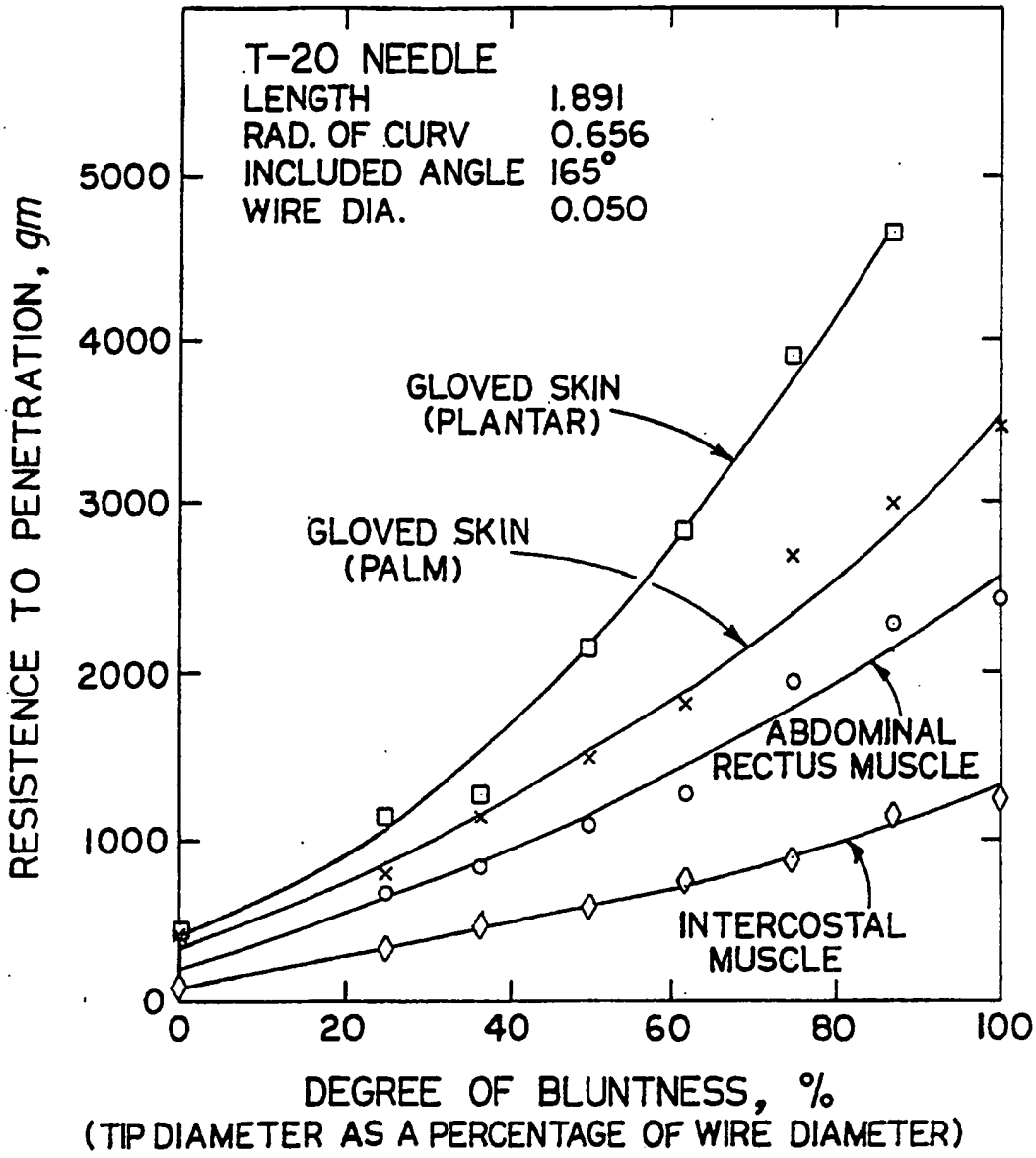
T-20 NEEDLE
LENGTH 1.891
RAD. OF CURV 0.656
INCLUDED ANGLE 165°
WIRE DIA. 0.050
GLOVED SKIN (PLANTAR)
GLOVED SKIN (PALM)
ABDOMINAL RECTUS MUSCLE
INTERCOSTAL MUSCLE
RESISTENCE TO PENETRATION, gm
5000
4000
3000
2000
1000
0
0
20
40
60
80
100
DEGREE OF BLUNTNESS, %
(TIP DIAMETER AS A PERCENTAGE OF WIRE DIAMETER)

Fig. 1

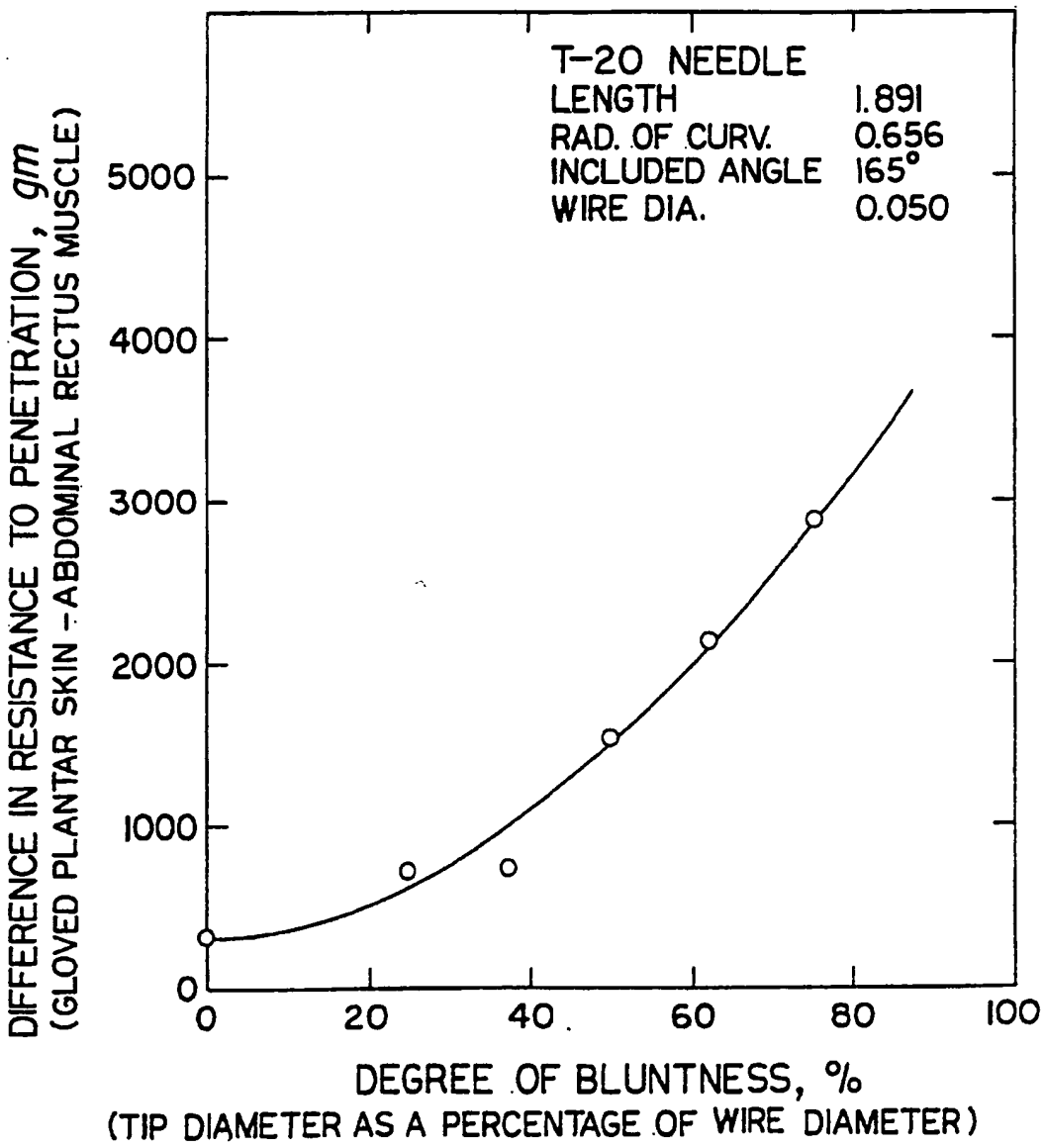
T-20 NEEDLE
LENGTH 1.891
RAD. OF CURV. 0.656
INCLUDED ANGLE 165°
WIRE DIA. 0.050
DIFFERENCE IN RESISTANCE TO PENETRATION, gm
(GLOVED PLANTAR SKIN - ABDOMINAL RECTUS MUSCLE)
5000
4000
3000
2000
1000
0
0
20
40
60
80
100
DEGREE OF BLUNTNESS, %
(TIP DIAMETER AS A PERCENTAGE OF WIRE DIAMETER)

Fig. 2

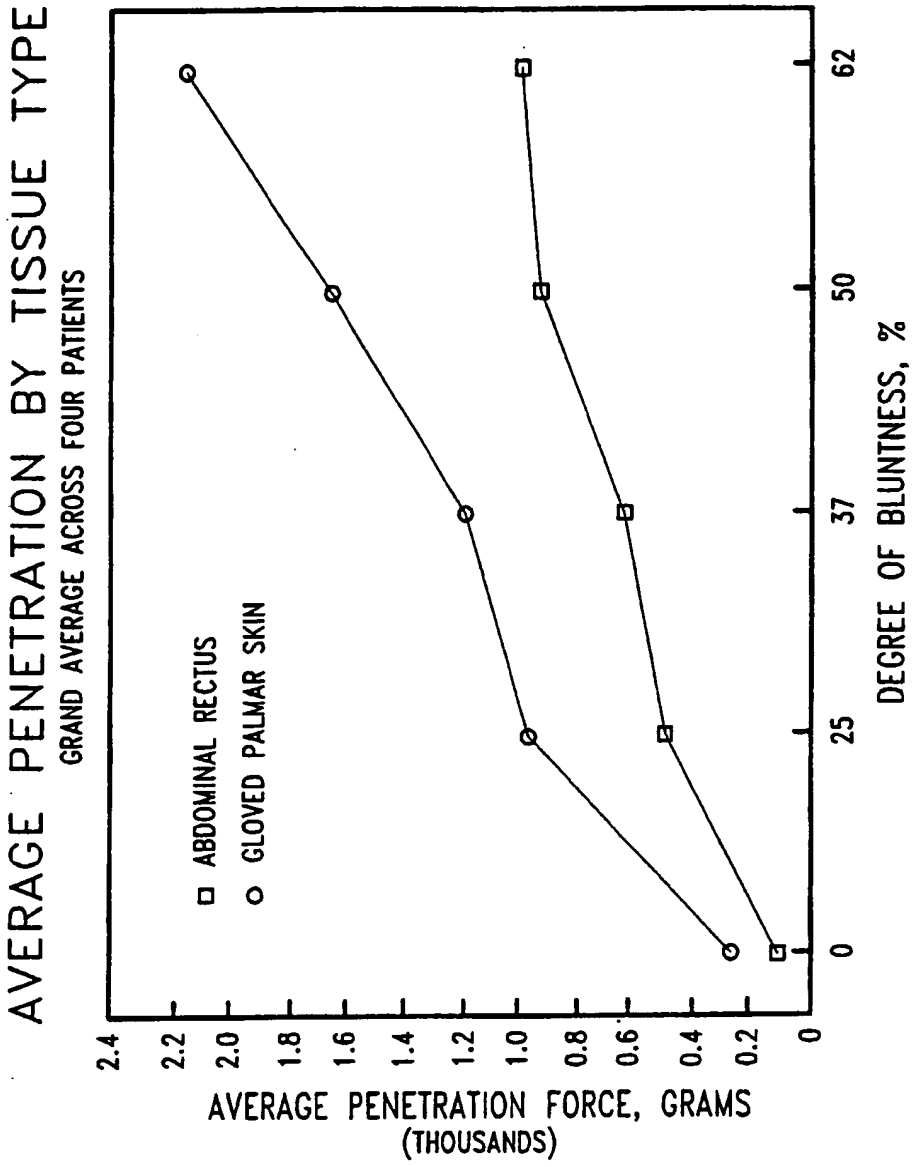
AVERAGE PENETRATION BY TISSUE TYPE
GRAND AVERAGE ACROSS FOUR PATIENTS
ABDOMINAL RECTUS
GLOVED PALMAR SKIN
AVERAGE PENETRATION FORCE, GRAMS
(THOUSANDS)
2.4
2.2
2.0
1.8
1.6
1.4
1.2
1.0
0.8
0.6
0.4
0.2
0
0
25
37
50
62
DEGREE OF BLUNTNESS, %

Fig. 3

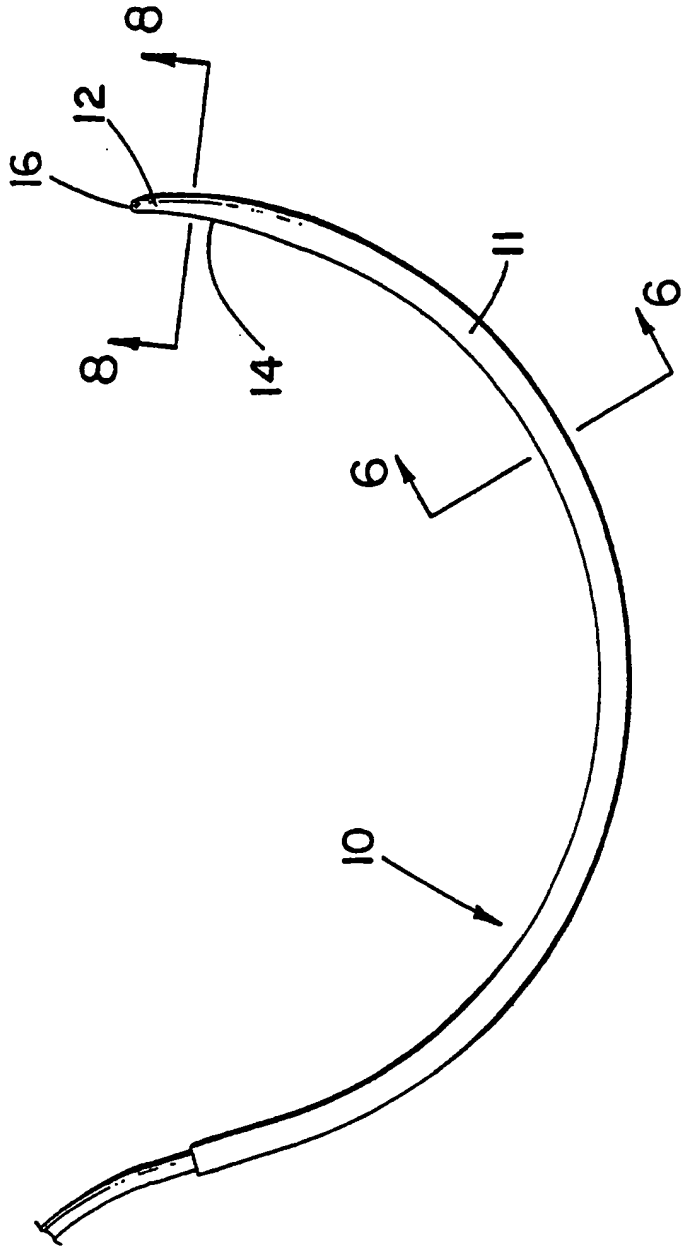

Fig. 4

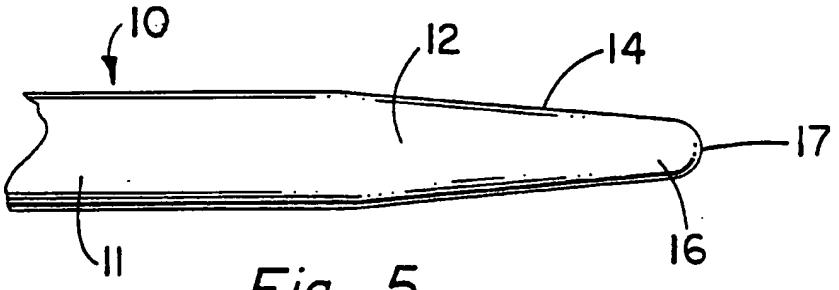

Fig. 5

Fig. 6

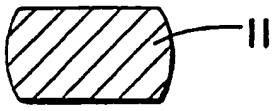

Fig. 8

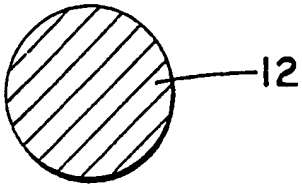

Fig. 7